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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,933	11/26/2001	Beth E. Drees	ECH-001	8812

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EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/991,933

**Applicant(s)**

DREES ET AL.

**Examiner**

Gary W. Counts

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/06/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Status of the claims**

The amendment filed October 21, 2004 is acknowledged and has been entered. Also the Declaration filed October 21, 2004 is acknowledged and has been entered.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 49-59 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is vague and indefinite because it is unclear if the substrate phosphoinositide lipid has been placed in another solution with the phosphoinositide kinase and then added to the analyte solution or if the protein having the phosphoinositide lipid recognition motif, the substrate and the competing lipid have all been added to the analyte solution. Applicant is reminded that in the event Applicant amends the claims, Applicant is required to show support in the specification (page and line numbers) for the amendment to the claims.

Claim 49 is vague and indefinite because it is unclear what relationship exists between the target lipid and the phosphoinositide kinase activity. The claim lacks correlation of the variation of signal to the target ligand and to the kinase activity.

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Claim 59 is vague and indefinite because it is unclear what relationship exists between the additional competing and noncompeting lipids and the unknown lipids and competing lipids of claim 49. For example, does the protein having a phosphoinositide lipid recognition motif also recognize the additional competing and noncompeting lipids. Also, it is unclear if these additional competing and noncompeting lipids are phosphoinositide lipids. See also deficiency found in claim 67.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 60-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czech et al (US 6,194,173) in view of Boguslaski et al (US Patent 5,420,016).

Czech et al disclose "general receptors for phosphoinositide" or GRPs (protein having a phosphoinositide lipid recognition motif). Czech et al disclose that these GRPs exhibit high affinity binding to products of the lipid kinase phosphatidylinositol 3-OH (PI(3)Kinase) (col 3). Czech et al disclose that the GRP comprises a structurally and functionally modular protein having a PH domain (col 32). Czech et al disclose that GST can be fused to the PH region of the GRP. Czech et al disclose that these GRPs have high affinity for polyphosphoinositide. Particularly, PtdIns (3,4,5)P<sub>3</sub>. Czech et al disclose that GRPs have about two orders of magnitude greater than that of PtdIns(4,5)P<sub>2</sub> (competing phosphoinositide lipid)(col 68, lines 24-32). Czech et al disclose that the GRPs can be labeled with enzymes and used in ELISA assays (col 37). Czech et al disclose the immobilization of GRPs or their binding partner to streptavidin coated microtitier plates (col 46).

Czech et al differ from the instant invention in failing to specifically teach the components packaged into a kit.

Boguslaski et al disclose assembling various system components into a test kit. By assembling these components into test kits, it makes it more convenient and facile for the test operator (col 7, lines 8-11).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the various reagents and components as taught by Czech et al into kits such as taught by Boguslaski et al because Boguslaski shows that test kits make it more convenient and facile for the test operator and further because although Czech et al does not specifically teach these components in a kit, Czech teaches the uses of the components in assays and discloses throughout the patent that components can be placed in a kit.

With respect to the recitation "for the quantification of phosphoinositide kinase activity" as recited in the instant claims. This recitation is not given patentable weight because it is intended use of the kit and since Czech et al disclose the same components as recited in the instant claims. The components of Czech et al would be capable of quantifying phosphoinositide kinase and therefore the combination of Czech et al and Boguslaski et al reads on the instantly recited claims.

***Allowable Subject Matter***

7. Claims 49-59 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

8. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or suggest using the protein having a phosphoinositide lipid recognition motif for quantification of phosphoinositide kinase activity in a method as recited in the instant claims.

***Response to Arguments***

9. Applicant's arguments with respect to claims 49-67 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Epps et al (US 2003/0235865) discloses fluorescence-based assay for protein kinases. The method of the invention utilizes a competitive immunoassay to determine the amount of substrate that is phosphorylated during the course of a kinase reaction to yield a product as well as the phosphorylating activity of a kinase.

Goueli (US 6,753,157) discloses a method of quantitating the activity of a selected protein kinase on a peptide substrate.

Guthridge et al (US 2002/0177166) discloses the analysis of PI 3-kinase activity. Guthridge et al discloses immunoprecipitating phosphotyrosine containing proteins using antibodies.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
December 16, 2004



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12/31/04